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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,631	12/03/2005	Moon-Hee Sung	4240-134	5032

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PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER	
BLUMEL, BENJAMIN P	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,631	SUNG ET AL.	
	Examiner	Art Unit	
	BENJAMIN P. BLUMEL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *3 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 6-19* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4 and 6-19 are examined on the merits. In lieu of the translation of the foreign priority document, the species election for subgroup **i** has been withdraw. Claims 3 and 5 remain withdrawn from consideration since they are non-elected species.

Response to Arguments

Applicant's arguments filed April 11, 2008 have been fully considered but they are not persuasive. See responses below. However, the 35 U.S.C. 103(a) rejection primarily based on Sung et al. (US PGPub 2005/0249752) and Ho et al. (BBRC, 2004) has been withdrawn in lieu of applicant's translation of their foreign priority document.

Claim Rejections - 35 USC § 103

(New Rejection Necessitated by Translation of Foreign Priority Document)

Claims 1, 6-8, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sung et al. (US PGPub 2004/0253704 A1) and Herold (US PGPub 2005/0002953 A1).

The claimed invention is drawn to a recombinant lactic acid bacterium that expresses the SARS spike protein along with the pgsA gene. The spike protein is expressed on the surface of the bacteria and the spike protein is produced through culturing the recombinant bacteria.

Sung et al. teach the expression of viral antigens when recombinant *Lactobaccillus casei* bacteria (a lactic acid bacteria) contained the vector pHCE1LB with Hepatitis B antigen coding regions and genes for pgsA, pgsB and/or pgsC. The expression construct thereby expresses these proteins on the surface of the bacteria However, Sung et al. do not teach expressing SARS spike antigens. *See paragraphs [0060, 0070, 0150 and 0171].*

Hollard et al. teach the expression of SARS-CoV spike antigens by inserting an expression cassette into bacteria. *See paragraphs [0150] and [0159].*

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Sung et al. in order to generating a recombinant *Lactobacillus* that contains an expression vector encoding pgsA and a SARS spike protein. One would have been motivated to do so, given the suggestion by Sung et al. that the bacterium be used to express antigens of interest. There would have been a reasonable expectation of success, given the knowledge that SARS spike proteins can be expressed by bacteria through an expression vector/plasmid, as taught by Ho et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 112

(New Rejection Necessitated by Translation of Foreign Priority Document)

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is drawn to the vectors pHCE2LB:pgsA-SARS SA,

pHCE2LB:pgsA-SARS SC or pHCE2LB:pgsA-SARS SBC.

It is apparent that the claimed vectors are required to practice the claimed invention because they are a necessary limitation for the success of the invention as stated in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the claimed vectors. See 37 CFR 1.802. Therefore, access to the claimed vectors are required to practice the invention. The specification does not provide a repeatable method for making the claimed vectors without access to these vectors and it does not appear to be readily available material.

Deposit of the claimed vectors in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112., because the strains would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:
(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;
(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

(Prior Rejection Maintained) Claims 9-13 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for producing antibodies in mice against recombinant *Lactobacillus casei* expressing SARS spike SA and SC and nucleocapsid NB antigens, does not reasonably provide enablement for a vaccine for SARS or preventing SARS through a vaccine administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use or make the invention commensurate in scope with these claims.

Applicants argue that even though the SARS proteins claimed where not glycosylated, U.S. Patents: 7,078,507; 5,747,526 and 4,642,333 and PCT publication WO/2002/058725 demonstrate that such glycosylation is not critical for effectiveness at providing a vaccine.

In response, while the above cited patents and the international patent application do state that glycosylation is not essential, none of these documents claim a vaccine for SARS or a method of prevention relating to SARS-coronavirus infections. These documents also fail to claim a vaccine of any kind and they do not discuss the issue at hand, SARS-coronavirus vaccines/immunogenic composition. Furthermore, while patent literature may state preferred embodiments, characteristics, etc. the focal point of such documents originates in the claims. For example, when searching for HIV vaccines being disclosed/discussed in a specification over 4000 documents among available patent literature. However, when the search is restricted to HIV vaccines being claimed, no

U.S. Patent exists with such a product. Similarly, no U.S. Patent has been issued claiming a SARS-CoV vaccine, partially based on the state of the art not recognizing such a vaccine (see page 6 of previous Office action), just as with HIV. Lastly, while applicants claim a vaccine capable of preventing SARS, none of their working examples involved the defining characteristic of a "vaccine", testing some level of protection following challenge by a virulent strain/isolate of SARS-CoV (see page 7 of previous Office action).

Therefore, the rejection has been maintained for reasons of record.

Claim Objections

(Necessitated by Translation of Foreign Priority Document) Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Summary

Claims 2 and 4 are free of the art. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648